



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 25 1998

Ms. Margaret Johnson
Executive Administrator
Rainbow Light
P. O. Box 600
Santa Cruz, California 95061-0600

1696 '98 SEP -3 P2:14

Dear Ms. Johnson:

This is in response to your letter of August 19, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Rainbow Light is marketing the product "Flavored Echinacea Cold CareTM."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product by the use of the term "Cold Care" in the product name suggests that it is intended to prevent, treat or mitigate a disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

975-0163

LET214

Page 2 - Ms. Margaret Johnson

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#60826)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:8/25/98:docname:60826.adv:disc31

Rainbow Light

Nutritional Systems

Post Office Box 600

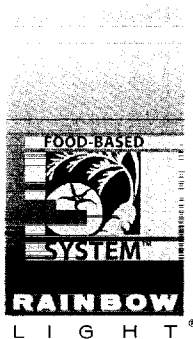
408-429-9089

Santa Cruz, California

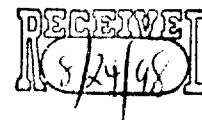
408-429-0189 Fax

95061-0600

1-800-635-1233



August 19, 1998



James Tanner
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St., S.W. (HFS-450)
Washington, D.C. 20204

Dear Mr. Tanner:

Pursuant to Section 6 of the Dietary Supplements Health and Education Act of 1994, Rainbow Light Nutritional Systems, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Flavored Echinacea Cold Care™. The statement of nutritional support reads as follows:

"Echinacea supports the body's natural defense response and resistance."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders this statement substantiated, truthful and non-misleading.

Sincerely,

Rainbow Light Nutritional Systems, Inc.

Margaret Johnson
Executive Administrator

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